



Texas Department of Health

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IMPORTANT NOTICE FOR DEVICE DISTRIBUTORS AND MANUFACTURERS

This notice is to advise you that the Texas Department of Health (TDH) has adopted amendments to 25 Texas Administrative Code (TAC), Sections 229.432 - 229.436, 229.439, 229.441, and 229.443, concerning the **Rules For Licensure of Device Distributors and Manufacturers**. Subsequent to review and recommendation by the Device Distributors and Manufacturers Advisory Committee, the proposed rules were approved by the Texas Board of Health (Board) and published in the December 1, 2000, issue of the *Texas Register* (25 TexReg 11876). Following a 30 day public comment period, final rules were adopted and published in the March 16, 2001, issue of the *Texas Register* (26 TexReg 2196). The rules became effective on March 19, 2001. A copy of the revised rules is enclosed for your reference. We strongly encourage you to read and become familiar with the amended sections.

The rule amendments clarify and update minimum standards for device distributors and manufacturers in order to conform with changes in federal requirements made pursuant to the U.S. Food and Drug Administration (FDA) Modernization Act of 1997. In addition, the amendments reflect changes necessitated as a result of a U.S. Supreme Court decision effectively negating FDA's attempts to regulate cigarette and smokeless tobacco products as devices. The rules contain new language related to combination products and the sale of contact lenses in order to reference statutory provisions passed by the 76th Texas Legislature and contained in Senate Bill 1236 and House Bill 749, respectively. The amendments clarify existing requirements for prescription devices as well as access to and retention of records required by these rules. Finally, the amendments update licensing procedures and customer assistance information.

These amendments were adopted under Health and Safety Code, Section 431.241, which provides TDH with authority to adopt necessary regulations pursuant to the enforcement of this Chapter; and under Health and Safety Code, Section 12.001, which provides the Board with authority to adopt rules for the performance of every duty imposed by law upon the Board, TDH, and the Commissioner of Health.

If you have any questions regarding this notice or desire additional information concerning the rule amendments, please contact the Bureau of Food and Drug Safety's Drugs and Medical Devices Division at (512) 719-0237.

<http://www.tdh.state.tx.us>

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